UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 1, 2005

MEMORANDUM:

Subject: Review of Product Chemistry and Hydrolysis Submissions for T 99-19 (40%)

To: Velma Noble, Product Manager, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

From: Talia Milano (D307164, D307185) and Robert Quick (D307183, D307184), Chemists
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Thru: Nader Elkassabany, Team Leader, Team Two
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Norm Cook, Branch Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

DP Barcode: D307164, D307183, D307184, D307185

EPA File Symbol: 3090-EEN

Decision #: 343925

MRID Number(s):
462804-07, -08, -09 (Product Chemistry)
RCC Study #: 841118 (Hydrolysis)

Case Type: New Registration

Data Submitter: Sanitized ® Inc.

PC Code: 107409

CAS#: 41591-87-1

Chemical Name: Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride

INTRODUCTION:

Sanatized® Inc. has submitted an application to the U.S. Environmental Protection Agency for a new registration of a new chemical active ingredient, T-99-19 (40% a.i.). The screen package indicates that there is an 80% TGAI for this chemical as well as a 40% end-use product. The registrant states that the product is produced by an integrated process and that there is no registration being sought for the technical product (80% active). The registrant is seeking registration only for the 40 % end-use product.

To support this new registration, the registrant has submitted product chemistry studies for the TGAI (MRID Nos. 462804-07, -08, -09) along with a hydrolysis study (RCC Study # 841118) for the new active ingredient, Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride. These studies have been submitted to meet the U.S. Environmental Protection Agency's Environmental Product Chemistry Data Requirements (OPPTS 830) and Environmental Fate Data Requirements (OPPTS 835.2110) in support of a new registration of T99-19 (40%). RASSB was not assigned the product chemistry data for the 40% Sanitized end-use product.

BACKGROUND:

The product is produced by an integrated system. It is anticipated to be marketed to industry as an antimicrobial liquid for textiles, and use sites include: shoes, draperies, mattress ticking, mattress pads, non-woven fabrics, sheets/towels, shower curtains, tenting tarpaulins, awnings, carpets/rugs, sleeping bags, outerwear apparel, socks, hosiery, underwear, upholstery, and air filters. The chemical will be intended to control the growth of microbes, and to hinder the occurrences of deterioration and discoloration in the presence of moisture.

SUMMARY OF DATA and CONCLUSIONS: See Data Evaluation Reports (DER).

RECOMMENDATIONS:

The registrant should address the product chemistry issues raised by RASSB as stated throughout the DER. The product chemistry submission is not acceptable because it is insufficient and assumptions are made, but not experimentally supported, about the behavior of the chemical. These specific issues are outlined in the DER. The waiver request for the hydrolysis study is being granted.

There is also a concern with the directions on the label, which indicate to the user, "Do not use [this product] in the manufacture or treatment of items that may come in contact with food." There is concern with the suggested uses because there is a possibility of dietary exposure, such as via non-woven fabrics, e.g. plastic table cloths or dishtowels. The registrant needs to clarify this use.

Subject: **Data Evaluation Report Product Chemistry Guideline: OPPTS 830**

From: Talia Milano 5/1/05 Robert Quick 5/3/2005
Talia Milano (D307164) and Robert Quick (D307183), Chemists
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

Thru: Norm Cook, Branch Chief 5/3/05
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

TEST MATERIAL:

Common name:	Sanitized, T 99-19
Active Ingredient:	Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride
PC Code:	107409
CAS No:	41591-87-1

REPORT:

MRID Number:	462804-07 (Volume 10)
Study Date:	March 13, 2004
Study Title:	PRODUCT CHEMISTRY DATA: T99-19 TGAI (80%) Series 830 (Group A)
MRID Number:	462804-08 (Volume 11)
Study Date:	March 13, 2004
Study Title:	PRODUCT CHEMISTRY DATA: T99-19 TGAI (80%) Series 830 (Group B)
MRID Number:	462804-09 (Volume 12)
Study Date:	March 13, 2004
Study Title:	PRODUCT CHEMISTRY DATA: T99-19 TGAI (80%) PRELIMINARY ANALYSIS Series 830.1700 (Group A)

EXECUTIVE SUMMARY:

The product chemistry data of T99-19 TGAI (80%) was evaluated alongside 40 CFR 158.190. This product chemistry guidance lists the physical and chemical characteristics data requirements for registering an end-use product. These requirements include a request for data for both the TGAI and an end-use product. Each volume pertaining to product chemistry is addressed individually. Under 40 CFR 158.190, Series 830.6314 (Oxidation/Reduction), 830.6315 (Flammability), 830.6316 (Explodability), 830.6317 (Storage Stability), 830.6319 (Miscibility), 830.6320 (Corrosion Characteristics), 830.6321 (Dielectric Breakdown Voltage), and 830.7100 (Viscosity) are not required.

STUDY DEFICIENCIES:

I. **80% Technical Product for OPPTS GLNs 830.1550-830.7950** Throughout the three volumes denoted for product chemistry, the following observations are made:

- *830.1550* (Product Identity and Composition)

The registrant has not submitted information with regards to the product identity and composition. The registrant must submit data as outlined in the guideline address this requirement.

- *830.1600* (Description of Materials Used to Produce the Product)

The registrant makes a reference to the names of the starting materials in the Confidential Statement of Formula. There is no discussion of the materials. The registrant must submit data as outlined in the guideline to address this requirement.

- *830.1620* (Description of Production Process)

The manufacturing process provided is on a laboratory scale, however, the proposed product will be produced on an industrial scale, which is important to consider. A laboratory procedure using a flask may not be indicative of the industrial scale production. The registrant states that a laboratory batch using glassware is 10-100 pounds. A batch of 10-100 pounds produced in laboratory glassware seems to be unrealistic. The guidelines should be referred to for guidance on the type of information that should be provided for the production of the TGAI in an industrial setting, or if there will be no registration of the TGAI, the process for pilot plant.

- *830.1670* (Discussion of Formation of Impurities)

It is specified on the Confidential Statement of Formula (CSF) that the TGAI product is a mixture of starting materials and byproducts. As a result, these byproducts are considered impurities. Due to this circumstance, there needs to be a discussion of the formation and nature of the impurities.

There is also an inert ingredient in the end use product, and not cleared for use by the Agency. Mr. Kerry Leifer, RD was consulted on 9/1/2004, and he was not able to find a clearance for this

inert ingredient. The registrant should either seek clearance for this inert ingredient or should replace that ingredient with an inert ingredient that the Agency has cleared for use in pesticide formulations.

- *830.1700* (Preliminary Analysis)

This guideline states in (2)(b) that "If the product consists solely of the technical grade active ingredient (TGAI) or is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI (the agency recognizes that this may not be appropriate for certain biological pesticides). The preliminary analysis of **5 batches** (if batch production) or **5 samples** (if continuous production) should be conducted..."

There was a submission of only one batch as the registrant claims it to be sufficient to demonstrate the amount of TGAI even though the impurities are present in excess of 0.1%.

There is also no data report such to fulfill the requirement of (2)(c), which requires a title page, table of contents, summary and introduction, materials and methods (analytical procedure, instrumentation, interferences, confirmatory techniques, time required for analysis, modifications, calculation, calibration factors, other), results and discussion, conclusions, certification, tables and figures, references, and appendices.

- *830.1750* (Certified Limits)

The registrant has provided certified limits on the CSF. However, additional batch analyses are required before AD can draw a conclusion on the validity of the claimed certified limits.

- *830.1800* (Enforcement Analytical Method)

The enforcement analytical method did not provide any detailed method with respect to the ^{13}CNMR technique that was employed, nor was there any data report. The registrant must provide a more detailed description of the method. The method should have sufficient detail that an independent chemist/analyst could use the method. The method must also include adequate validation data.

- *830.1900* (Submittal of Samples)

The registrant states that samples will be submitted upon request.

- *830.6302* (Color)

The color of the chemical is denoted to be beige, and this was concluded based on the technician's visual assumptions. There was no standard system that was used to identify the color, and section (b)(2)(iv) of this guideline states that if an alternative method is employed, it is recommended that the registrant consult with the Agency.

- *830.6303* (Physical State)

The registrant states that the product is a **pasty** solid. However, the technician that conducted the water solubility study indicates that the product is a solid. Clarification on the physical condition of the product is needed because of this inconsistency. Also, the registrant indicates that the product is completely soluble in water. However, after 30-75 minutes it undergoes polymerization. There is no data provided to supplement this claim.

- *830.6304* (Odor)

The odor was identified to be "characteristic" by the registrant. However, there is no indication of what the odor was characteristic of. An amine?

- *830.6313* (Stability to Normal and Elevated Temperature, Metals, and Metal Ions)

Under 40 CFR 158.190, the test of the stability of the TGAI to normal and elevated temperatures, metals, and metal ions is required. The registrant indicates that this is not applicable when in fact it is.

- *830.7000* (pH)

The registrant states that the collection of pH values was technically impossible to carry out because the texture of the product is a pasty solid. However, the registrant adds that the pH analysis was performed on a diluted TGAI, as provided in Attachment E of Volume 11. However, there is no indication as to whether Tap or D.I. water was used to dilute the material. Tap water can have impurities, which can affect the pH values obtained. In addition, there are no tabulated pH readings.

- *830.7050* (UV/Visible Absorption)

The registrant indicates that it is not possible to perform UV/Visible absorption analysis because the Si-Quats do not absorb in the range of the signal. There is no data provided to support this claimed attempt.

- *830.7200* (Melting Point/Melting Range)

The registrant provides the melting point range, but there is no data table or thorough discussion of the equipment that was employed. The registrant indicates, in Attachment F of Volume 11, the melting point range was determined by a visual test method.

- *830.7220* (Boiling Point/Boiling Range)

The registrant indicates that the boiling point was determined via differential scanning calorimetry. However, there is no data table provided or a record of instrumental output.

- *830.7300* (Density)

The registrant did not provide any data tables or calculations of the density and employed an oscillating densitimeter to provide the density value. As 830.7300 indicates, an oscillating densitimeter is allowed to be employed only if the substance is a liquid. It was determined by the registrant that the substance was a pasty solid; hence this technique used to determine the density is not consistent

- *830.7370* (Dissociation Constants in Water)

Under 40 CFR 159.190, this test is required for a TGAI. The registrant did not provide reason or evidence as for why this test was not conducted, other than the statement that, "Product is completely soluble in water however the product is not stable in water. The product polymerizes in 30-75 minutes. The product reacts (ionized) with water" (5 of 14 in Volume 11).

- *830.7840* (Column Elution) and *830.7860* (Water Solubility, Generator Column)

The registrant states that the product is unstable in water and that is why the preceding guideline requirements could not be fulfilled. This is further addressed in the hydrolysis DER.

- *830.7950* (Vapor Pressure)

The registrant provides that the Modified Waston Correlation Method was employed to determine the vapor pressure. However, there is no calibration, data, or validation of this approach. The EPA guideline provides examples of methods that can be employed to determine the vapor pressure and outlines the required information.

II. Product Chemistry Guidelines for the Physical and Chemical Properties for the 40% End-Use Product

RASSB was not assigned the product chemistry data for the 40% Sanitized end-use product. Those data were assigned to the Product Science Branch for review (Personal communication between Robert Quick, RASSB and Tracy Lantz, RMB I on 9/1/2004).

Reviewers Comments and Conclusions:

This submission did address the Product Chemistry Guidelines, Series 830. The registrant has either submitted the required product chemistry studies or explained why he does not believe the data need to be submitted. **There were numerous deficiencies in the product chemistry submission and RASSB believes it to be insufficient for fulfilling product chemistry requirements.**

Subject: Data Evaluation Report Hydrolysis (as a function of pH) Guideline: OPPTS 835.2110

From: Talia Milano 5/1/05 Robert Quick 5/3/2005
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Antimicrobials Division (7510C)

Thru: Norm Cook, Branch Chief 5/3/05
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510C)

TEST MATERIAL:

Common name:	Sanitized, T 99-19
Active Ingredient:	Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride
PC Code:	107409
CAS No:	41591-87-1

REPORT:

MRID Number:	N/A, submission includes project ID # 841118 (Volume 22)
Study Date:	March 13, 2004
Study Title:	HYDROLYSIS OF SANITIZED T99-19 AT DIFFERENT pH VALUES WITH T99-19 TGAI (80%) Series 835.2110

EXECUTIVE SUMMARY:

The environmental fate study of T99-19 TGAI (80%) was evaluated alongside the OPPTS harmonized test guideline 835.2110 Guidelines, Hydrolysis as a Function of pH. Hydrolysis in itself refers the decomposition of a chemical compound via a reaction with water. An example of such is demonstrated by the commonly understood reaction, the dissociation of a salt in water. For this reason, a hydrolysis study can only be performed on chemicals that are water-soluble. Based on the various product chemistry conclusions and statements, it appeared that the compound was water soluble, and for that reason, a hydrolysis study was assumed to be able to be performed.

Sanitized®Inc. is requesting a waiver for the hydrolysis data requirements. This request has been supplemented with four rationales. These are:

(1) An expert statement indicates that the study of this nature is not feasible on this product. (Attachment A)
(2) The expert statement references the water solubility study in which the product is found to be soluble in water, but unstable, because it polymerizes in 30-75 minutes. Several pages were extracted from this study and are attached as Attachment B.
(3) The registrant states that the Agency granted a waiver for the hydrolysis study data requirement for Requat, PC code 169160 (EPA and Company Correspondence: Attachment C). The registrant believes that Requat and this product, T99-19, belong to the same class of quaternary ammonium compounds: trimethoxysilyl. Attachment D provides the chemical structures of these compounds in an attempt to support the claimed similarity.
(4) The intended uses for the products are solely for the treatment of textiles, and therefore could be considered as indoor non food use. It is being noted that these use patterns are the same uses already established on the other silyl quat product: Requat.

To address this hydrolysis submission, each attachment is treated separately concerning the material and methods, experimental setup (if applicable), and any deficiencies or concerns. While there are some deficiencies in the submission, it appears that based on scientific literature, the chemical components of T99-19, and the observed chemical behavior as noted by the registrant, that a hydrolytical analysis is extremely difficult. The submission does support that hydrolysis is occurring; but that the components of the test substance and its constituents can not be quantified. So to conclude, RASSB does believe that hydrolysis does occur when this chemical is placed in water, but also acknowledges the difficulty of the analysis of a compound with silane derivatives, and for this reason, will waive the hydrolysis requirement. However, should any additional uses be added, a hydrolysis study may be required.

REVIEW OF SUBMISSION:

Attachment A (Hydrolysis of Sanitized®T99-19 at Different pH Values, RCC Study Number 841118)

This attachment includes a title page of RCC Study Number 841118, Hydrolysis of Sanitized ® T99-19 at Different pH Values, and a statement made by Mrs. Alessandra Tognucci, Study Director and Dr. Ute Schmiedel, Head of Analytical Chemistry. It is stated that Sanitized ® T99-19 could be detected qualitatively by LC-MS, but could not be determined quantitatively due to the strong adsorption of the test item to the vessels and HPLC equipment. The technicians attempted to wash the equipment with different solvents and mixtures, but were not successful in extracting the product for analysis. It is also stated that RCC Study 841103 (Attachment B) depicts the attempt to determine the water solubility of this chemical. Through observing the behavior of the chemical in water, it was judged 75 minutes after preparation to be viscous and white or yellow in color. Both Mrs. Teognucci and Dr. Schmiedel believe that this behavior in the water solubility study supports that Sanitized ® T99-19 is hydrolyzing in aqueous solution.

Furthermore, the expert statement concludes with the decision not to perform the hydrolysis test on this chemical because there is no suitable analytical method available to monitor the degradation of the test substance.

The registrant indicates that there is an observed instability of this compound in water. This is interpreted to be indicative of the polymerization that is claimed to have occurred after 30-75 minutes. In the product chemistry submission it was stated numerous times throughout that ***the product is soluble in water****, but not stable in water. Due to the initial statement that T-99-19 is soluble in water, RASSB initially presumed that the hydrolysis study is required.*

The technician indicates that there was an attempt to deal with the analytical difficulties of this chemical. There was no data or chromatograms available to verify this statement of attempting to extract the test substance from the HPLC equipment and vessels.

Attachment B (Determination of the Water Solubility of Sanitized® T99-19 including effect of pH and Temperature, RCC Study # 841103)

This attachment is a study that is stated to serve the purpose of **evaluating the solubility** of Sanitized ® T99-19 in aqueous buffer solutions (pH 5, 7, 9) at $10^{O}C$, $20^{O}C$, and $30^{O}C$. However the structure of this adopted methodology does not match the water solubility guidelines which fall under OPPTS 830.7840 (Water Solubility: Column Elution Method; Shake Flask Method) and OPPTS 830.7860 (Water Solubility (Generator Column Method)). Rather, the structure of the experimental layout more closely follows OPPTS 835.2110 (Hydrolysis as a function of pH), and that is why it has been compared with OPPTS 835.2110 guidelines.

A. MATERIALS:

1) **Test Material** : Sanitized ® T99-19
Description: Solid, Beige

2) **Buffer Solution:** OPPTS guidelines provide guidance as to how to generate buffer solutions, as seen in Table 13 of OPPTS 835.2110(d)(2)(I)(A)(*2*).

The registrant has not followed the guidelines or provided the composition of the buffer solutions employed in this method.

Table 1: Description of the Buffer Solutions

pH	Composition
5	No discussion, other than that it is Citrate
7	No discussion, other than that it is Phosphate
9	No discussion, other than that it is Borate

B. EXPERIMENTAL CONDITIONS:

Precursory Studies (RCC Study # 841103)**:**

The registrant indicates that there was no analytical method that could be developed for quantification of the test item in aqueous solutions due to the physical properties of the test substance. Because of this, the concentration of the substance in the test samples could not be determined, and hence, water solubility could not be conducted on this chemical. The registrant cites, RCC Study 841120, Analytical Work (Method for Sanitized ® T99-19 in aqueous media), as a study to support this claim of incapability to devise a sufficient analytical method to quantify this chemical in an aqueous media.

RASSB has received a copy of this study, RCC #841120, upon request; it was not submitted with the original submission. This study is addressed in **Supplemental Experiments**

Table 2: Experimental Parameters of Solubility Study - RCC Study # 841103

Parameters	Details
Duration of the study	75 minutes
Test concentrations (mg./L)	0.5g of the test item in 0.5mL of water (room temperature analysis) 1g of the test item with 1mL of the buffer solution

Parameters	Details
No. of replications	Duplicate, but data only provided for single samples for each pH level (5,7,9) at each temperature of 10, 20, 30 ^{o}C
Test apparatus	Visual method

Supplemental Experiments:

The cited, RCC Study 841120 (Analytical Work (Method for Sanitized ® T99-19 in aqueous media) is addressed in this portion of the document. This study states that hydrolysis occurs when the chemical is placed in an aqueous media.

This study employed the standard and the technician conducted an analysis through using an HPLC/MS system. The study indicates that the test item is not stable in bidistilled water, but there are two products that were detected at two different masses. The main product, which is $C_{22}H_{50}NO_3Si^+$, and the hydrolysis product, $C_{19}H_{44}NO_3Si^+$ were both said to be detected before storage of the standard solution. After the storage, the technician states in the report that, "only the hydrolysis peak was found." However, there was an inability to quantify the compound. A second test method was attempted with different HPLC conditions, and both the test item and hydrolysis substance were adsorbed on the HPLC column. The summary of this study states that, "Sanitized ® T99-19 and its hydrolysis product could be detected qualitatively by LC MS...[but] could not be determined quantitatively due to the strong adsorption of the test item to the vessels and HPLC-equipment."

RASSB did not analyze this study in terms of compliance because it was not part of the original submission but was provided to the reviewer per a personal request. The study did not include any raw data or chromatograms supporting the claim. However, due to the properties of silicone, which is a constistuent of the molecule, this difficulty in quantifying the product and its hydrolytical product is anticipated.

C. ANALYTICAL METHODS (RCC Study # 841103):

Prior to testing the test substance at different pH's and temperatures, an analysis was carried out at room temperature. It is stated that the test item mixture with water was clear and yellow with many air bubbles. After 30 minutes to 1 hr, the consistency of the mixture was observed to change to a yellow-white semisolid. To this consistency, 25mL of water were added and the mixture was stirred at room temperature, and the mixture foamed and was not resolvable.

There is no identification of this substance that formed as a result of this mixture of the product and water. RASSB is uncertain if this substance is indicative of a chemical change, or if it is the hydrolytical product.

Furthermore, for the analyses that were carried out with the varying pH's and temperatures, the visual observations were recorded. It was observed that the solution became viscous and the agitator stopped stirring anywhere from 30-75 minutes after mixing in all of the experimental trials.

RASSB concludes from the data, that for the initial 30 minutes, the test substance appears to be in a somewhat liquid form and then undergoes a chemical change. The procedure in which this data was obtained is not in correspondence with GLP practices, and there is no method validation. The registrant does not provide raw data that displays the incapability of the various experimental methods that were attempted to quantify this chemical. It will be useful for the registrant to identify the product that is forming.

D. RESULTS AND DISCUSSION

The registrant states that the change in color and viscosity noted in the water solubility study are indicative that Sanitized ® T99-19 is not stable in aqueous solution. As a result the solubility can not be determined for this chemical.

RASSB finds that the water solubility study was submitted to support the claimed instability of T99-19 in water. The instability was presented to support as to why a hydrolysis can not be performed. RASSB believes this misleading statements that T99-19 is water soluble can be disregarded because of the behavior supported within this submission.

Attachment C&D

Attachment C contains several letters depicting the process in which the registrant proposed to the Agency to consider a hydrolysis waiver request for REQUAT (PC Code 169160), which was eventually granted (Sender: EPA, letter dated 6/19/97). This letter was included because the registrant believes that the same waiver should be granted for T99-19. The registrant states that T 99-19 and REQUAT would belong to the same chemical class of quaternary ammonium compounds if there was a class that existed; trimethoxysilyl. It is also being noted that Sanitized is intended for textile treatment, which indicates an indoor non-food use. The registrant indicates that this use is identical to what is already established on the already registered product, REQUAT.

RASSB does not agree with textile treatment being limited to indoor non-food use because there is uncertainty with the direction of the label. The product may be used in non-woven fabrics. Some non-woven fabrics could be used for food contact, e.g. plastic table cloths (See 40 CFR 180.539, d- limonene on tablecloths).

With regards to the claim of REQUAT and T99-19 belonging to a chemical class trimethoxysilyl, a letter provided with the submission (Sender: EPA, dated 2/25/04), PR Notice 88-2 is addressed and indicated to contain four clusters of quaternary ammonium compounds for the purpose of developing a database for quaternary ammonium compounds. Data can be used form one quaternary ammonium compound in a **cluster** to support another quaternary compound

in the same **cluster.** Both REQUAT and Sanitized ® T99-19 are trimethoxysilyl quaternary ammonium compounds (as exhibited in Attachment D) **although there are no cluster categories for such.**

RASSB acknowledges the similarity between T99-19 and REQUAT in terms of structure, but the argument that both chemicals belong to the same cluster is not legitimate based on this correspondence. There is no class of quaternary ammonium compounds that has been recognized scientifically, so the class argument can not be used as a basis for waiving the hydrolysis request.

Reviewers Comments and Conclusion:

The registrant does support that the water solubility test generates results that do not allow for the ease of quantification (RC # 841103). In addition, the study that was submitted per personal request of the reviewer (RC # 841120) addresses the registrant's claimed attempt to develop an analytical method. Neither one of the studies was conducted under GLP practices, and make an acknowledgement that there is a formation of a hydrolytical product.

RASSB conducted a literature search to examine this claim that Sanitized polymerizes when it is placed in water. The chemical, octadecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride, is almost identical to Sanitized (Dimethyl tetradecyl-[3-(trimethoxysilyl)-propyl] ammonium chloride). Octadecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride's empirical formula is $C_{26}H_{58}ClNO_3Si$ and Sanitized's is, $C_{22}H_{50}ClNO_3Si$. The structures of octadecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride (Figure 1) and Sanitized (Figure 2) are included to serve as a visual reference.

Figure 1: $C_{26}H_{58}ClNO_3Si$

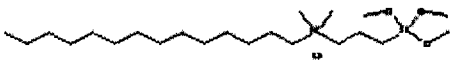

Figure 2: $C_{22}H_{50}ClNO_3Si$

It can be observed that the 4 less carbons on the hydrophobic tail of Sanitized is the only difference between these two molecules.

Two papers have been acquired in the literature search.

"Formation of Metal Nanoparticles in Multilayered Poly(octadecylsiloxane) As Revealed by Anomalous Small-Angle X-ray Scattering," addresses the functionality of the silanol group. "It has been demonstrated that the polymeric condensate consists of highly uniform, pillared microcrystallites in which the inorganic siloxy backbones form periodic layers, each containing a monomolecular layer of intercalated water, separated by crystalline assemblies of alkyl chains" (Svergun 3552). The paper more specifically addresses the use of a polymeric matrix as a medium for metal nanoparticle formation, which is beyond the scope of this review. The significant information in this paper is that the siloxy backbones are the driving force for the formation of this polymeric matrix that results from the chemical being in the presence of water.

The second paper, "*Functional Polymer Colloids with Ordered Interior,"* specifically examines the behavior of Octadecyldimethyl(3-trimethoxysilylpropyl)ammonium chloride (ODMAC1). "Hydrolytic condensation of pure ODMAC1 resulted in the lamellar phase...no details were provided on the structure of these polymer colloids...polymer colloids based on ODMAC1 can grant stable ordering under various reaction conditions, since ordering is provided by hydrophobic interactions of very long (C_{18}) hydrophobic tails" (Bronstein 1101).

Through the behavior indicated in the water solubility study and the literature search conducted by RASSB, it does appear that Sanitized hydrolyzes and consequently polymerizes in water. Because of the chemical nature and behavior of the siloxy groups and hydrocarbon tails, the claimed difficulty of analyzing this chemical **is acceptable and the hydrolysis waive can be granted**. If any additional uses are added in the future, a hydrolysis study may be required.

Works Cited:

Both of these articles are printed in ACS published journals and can also be accessed electronically through http://pubs.acs.org

Formation of Metal Nanoparticles in Multilayered Poly(octadecylsiloxane) As Revealed by Anomalous Small-Angle X-ray Scattering
Svergun, D. I.; Kozin, M. B.; Konarev, P. V.; Shtykova, E. V.; Volkov, V. V.; Chernyshov, D. M.; Valetsky, P. M.; Bronstein, L. M.;
Chemistry of Materials.; **(Article); 2000**; *12*(12); 3552-3560.

Functional Polymer Colloids with Ordered Interior
Bronstein, L. M.; Linton, C.; Karlinsey, R.; Stein, B.; Timofeeva, G. I.; Svergun, D. I.; Konarev, P. I.; Kozin, M.; Tomaszewski, J.; Werner-Zwanziger, U.; Zwanziger, J. W.;
Langmuir; **(Article); 2004**; *20*(4); 1100-1110